



## General

#### Guideline Title

Cervical insufficiency and cervical cerclage.

## Bibliographic Source(s)

Brown R, Gagnon R, Delisle MF, Maternal Fetal Medicine Committee, Gagnon R, Bujold E, Basso M, Bos H, Brown R, Cooper S, Crane J, Davies G, Gouin K, Menticoglou S, Mundle W, Pylypjuk C, Roggensack A, Sanderson F, Senikas V. Cervical insufficiency and cervical cerclage. J Obstet Gynaecol Can. 2013 Dec;35(12):1115-27. [156 references] PubMed

## **Guideline Status**

This is the current release of the guideline.

## Recommendations

# Major Recommendations

The quality of evidence (I-III) and classification of recommendations (A-E, L) are defined at the end of the "Major Recommendations."

#### Diagnosis of Cervical Insufficiency

- 1. Women who are pregnant or planning pregnancy should be evaluated for risk factors for cervical insufficiency. A thorough medical history at initial evaluation may alert clinicians to risk factors in a first or index pregnancy. (III-B)
- 2. Detailed evaluation of risk factors should be undertaken in women following a mid-trimester pregnancy loss or early premature delivery, or in cases where such complications have occurred in a preceding pregnancy. (III-B)

#### Management of Cervical Insufficiency

#### Prophylactic Transvaginal Cerclage

- 3. In women with a history of cervical insufficiency, urinalysis for culture and sensitivity and vaginal cultures for bacterial vaginosis should be taken at the first obstetric visit and any infections so found should be treated. (I-A)
- 4. Women with a history of three or more second trimester pregnancy losses or extreme premature deliveries, in whom no specific cause other than potential cervical insufficiency is identified, should be offered elective cerclage at 12 to 14 weeks of gestation. (I-A)

#### Prophylactic Transabdominal Cerclage

- 5. In women with a classic history of cervical insufficiency in whom prior vaginal cerclage has been unsuccessful, abdominal cerclage can be considered in the absence of additional mitigating factors. (II-3C)
- 6. Women who have undergone trachelectomy should have abdominal cerclage placement. (II-3C)

#### Emergency Cerclage

7. Emergency cerclage may be considered in women in whom the cervix has dilated to <4 cm without contractions before 24 weeks of gestation. (II-3C)

### Conservative Observational Management

Note: See the original guideline document for the five steps of conservative management.

8. Women in whom cerclage is not considered or justified, but whose history suggests a risk for cervical insufficiency (1 or 2 prior mid-trimester losses or extreme premature deliveries), should be offered serial cervical length assessment by ultrasound. (II-2B)

Cerclage Based on Ultrasound Measurement of Cervical Length

- 9. Cerclage should be considered in singleton pregnancies in women with a history of spontaneous preterm birth or possible cervical insufficiency if the cervical length is ≤25 mm before 24 weeks of gestation. (I-A)
- 10. There is no benefit to cerclage in a woman with an incidental finding of a short cervix by ultrasound examination but no prior risk factors for preterm birth. (II-1D)

#### Multiple Gestations

- 11. Present data do not support the use of elective cerclage in multiple gestations even when there is a history of preterm birth; therefore, this should be avoided. (I-D)
- 12. The literature does not support the insertion of cerclage in multiple gestations on the basis of cervical length. (II-1D)

#### Definitions:

Quality of Evidence Assessment\*

- I: Evidence obtained from at least one properly randomized controlled trial
- II-1: Evidence from well-designed controlled trials without randomization
- II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group
- II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category
- III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees
- \*Adapted from the Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.

#### Classification of Recommendations†

- A. There is good evidence to recommend the clinical preventive action
- B. There is fair evidence to recommend the clinical preventive action
- C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making
- D. There is fair evidence to recommend against the clinical preventive action
- E. There is good evidence to recommend against the clinical preventive action
- L. There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making
- †Adapted from the Classification of Recommendations criteria described in the Canadian Task Force on Preventive Health Care.

# Clinical Algorithm(s)

An algorithm titled "Flow Diagram" is provided in the original guideline document.

# Scope

## Disease/Condition(s)

Cervical insufficiency

## **Guideline Category**

Evaluation

Management

Risk Assessment

Screening

Treatment

## Clinical Specialty

Obstetrics and Gynecology

Surgery

## **Intended Users**

Physicians

## Guideline Objective(s)

The purpose of this guideline is to provide a framework that clinicians can use to determine which women are at greatest risk of having cervical insufficiency and in which set of circumstances a cerclage is of potential value

# **Target Population**

Women who are pregnant or planning pregnancy

## Interventions and Practices Considered

- 1. Medical history
- 2. Risk assessment
- 3. Urinalysis and vaginal culture
- 4. Serial cervical length assessment by ultrasound
- 5. Vaginal or abdominal cervical cerclage (as indicated)

# Major Outcomes Considered

• Timing of surgical treatment

- Surgical effectiveness
- Maternal and fetal morbidity and mortality

# Methodology

## Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Searches of Unpublished Data

## Description of Methods Used to Collect/Select the Evidence

Published literature was retrieved through searches of PubMed or MEDLINE, CINAHL, and The Cochrane Library in 2012 using appropriate controlled vocabulary (e.g., uterine cervical incompetence) and key words (e.g., cervical insufficiency, cerclage, Shirodkar, cerclage, MacDonald, cerclage, abdominal, cervical length, mid-trimester pregnancy loss). Results were restricted to systematic reviews, randomized control trials/controlled clinical trials, and observational studies. There were no date or language restrictions. Searches were updated on a regular basis and incorporated in the guideline to January 2011.

Grey (unpublished) literature was identified through searching the websites of health technology assessment and health technology related agencies, clinical practice guideline collections, clinical trial registries, and national and international medical specialty societies.

### Number of Source Documents

Not stated

# Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

# Rating Scheme for the Strength of the Evidence

Quality of Evidence Assessment\*

I: Evidence obtained from at least one properly randomized controlled trial

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III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

\*Adapted from the Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.

# Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

## Description of the Methods Used to Analyze the Evidence

The quality of evidence in this document was rated using the criteria described in the Report of the Canadian Task Force on Preventive Health Care (see the "Rating Scheme for the Strength of the Evidence" field).

## Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

Not stated

## Rating Scheme for the Strength of the Recommendations

Classification of Recommendations†

- A. There is good evidence to recommend the clinical preventive action
- B. There is fair evidence to recommend the clinical preventive action
- C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making
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- L. There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making †Adapted from the Classification of Recommendations criteria described in the Canadian Task Force on Preventive Health Care.

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### Method of Guideline Validation

Internal Peer Review

# Description of Method of Guideline Validation

This clinical practice guideline has been prepared by the Maternal Fetal Medicine Committee, reviewed by the Clinical Practice Obstetrics Committee, and approved by the Executive and Council of the Society of Obstetricians and Gynaecologists of Canada.

# Evidence Supporting the Recommendations

# Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

# Benefits/Harms of Implementing the Guideline Recommendations

#### Potential Benefits

Appropriate diagnosis and management of women at greatest risk of having cervical insufficiency and the appropriate use of cervical cerclage

#### Potential Harms

#### Complications

- Three randomized clinical trials have shown that cerelage is associated with increased medical interventions and doubles the risk of puerperal pyrexia. The use of tocolytics increases with cerelage, as does the rate of hospital admissions, and one study found a higher rate of Caesarean sections. However, the risk and nature of complications is influenced by whether the cerelage is inserted electively or as an emergency with membranes bulging through the cervix. The complications reported with cerelage include sepsis, premature rupture of membranes, premature labour, cervical dystocia, cervical laceration at delivery (11% to 14%), and hemorrhage.
- However, meta-analysis of a number of studies has not confirmed higher rates of chorioamnionitis or preterm pre-labour membrane rupture
  in women managed with cerclage than in those managed by other means. Although cervical dystocia is frequently cited as a complication of
  cerclage due to cervical scarring, data do not support its being truly attributable to cerclage; the increased risk of cervical laceration,
  however, although it appears to be unrelated to the timing of the removal of the cerclage, can be attributed to the cerclage.

# **Qualifying Statements**

## **Qualifying Statements**

This document reflects emerging clinical and scientific advances on the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Local institutions can dictate amendments to these opinions. They should be well documented if modified at the local level. None of these contents may be reproduced in any form without prior written permission of the Society of Obstetricians and Gynaecologists of Canada (SOGC).

# Implementation of the Guideline

# Description of Implementation Strategy

An implementation strategy was not provided.

# Implementation Tools

Clinical Algorithm

Foreign Language Translations

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

#### **IOM Care Need**

#### **IOM Domain**

Effectiveness

# Identifying Information and Availability

## Bibliographic Source(s)

Brown R, Gagnon R, Delisle MF, Maternal Fetal Medicine Committee, Gagnon R, Bujold E, Basso M, Bos H, Brown R, Cooper S, Crane J, Davies G, Gouin K, Menticoglou S, Mundle W, Pylypjuk C, Roggensack A, Sanderson F, Senikas V. Cervical insufficiency and cervical cerclage. J Obstet Gynaecol Can. 2013 Dec;35(12):1115-27. [156 references] PubMed

## Adaptation

Not applicable. The guideline was not adapted from another source.

#### Date Released

2013 Dec

## Guideline Developer(s)

Society of Obstetricians and Gynaecologists of Canada - Medical Specialty Society

## Source(s) of Funding

Society of Obstetricians and Gynaecologists of Canada

## Guideline Committee

Maternal Fetal Medicine Committee

# Composition of Group That Authored the Guideline

Principal Authors: Richard Brown, MD, Montreal QC; Robert Gagnon, MD, Montreal QC; Marie-France Delisle, MD, Vancouver BC

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## Financial Disclosures/Conflicts of Interest

Disclosure statements have been received from all members of the committee.

#### **Guideline Status**

This is the current release of the guideline.

## Guideline Availability

Electronic copies: Available from the Society of Obstetricians and Gyna	aecologists of Canada (SOGC) Web site	. Also
available in French from the SOGC Web site	].	

Print copies: Available from the Society of Obstetricians and Gynaecologists of Canada, La société des obstétriciens et gynécologues du Canada (SOGC) 780 promenade Echo Drive Ottawa, ON K1S 5R7 (Canada); Phone: 1-800-561-2416.

## Availability of Companion Documents

None available

#### Patient Resources

None available

#### **NGC Status**

This NGC summary was completed by ECRI Institute on April 1, 2014. The information was verified by the guideline developer on April 28, 2014.

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